

5. 510(k) Summary

JUN 23 2010

Manufacturer: U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050
Gyeong-Je Kwon, Regulatory Affairs Specialist

Sponsor: U & I Corporation
529-1, Yonghyun-dong, Uijungbu
Kyunggi-Do, Korea 480-050

Sponsor Contact: Gyeong-Je Kwon, Regulatory Affairs Specialist

Date Prepared: June 21, 2010

Device Name: Trade Name: *Dyna Locking Trochanteric Nail™*

Common Name: Intramedullary Fixation System

Classification Name: Intramedullary Fixation Rod (HSB), per 21 CFR 888.3020

Product Code: HSB

Predicate Devices: Grosse and Kempf Locking Nail System (K860756)
Delta II Femoral Nail (K981529)
T2 Femoral Nail (K081152)
Proximal Femoral Nail System (K973240)
Dynamic Hip Screw (K953607)

Description of Device:

The *Dyna Locking Trochanteric Nail™* consists of intramedullary rod, neck screw assembly (neck screw + wedge wing), locking screw, fixed nail cap, slidable nail cap, end cap, and short end cap. The rods are available in a variety of diameters and lengths and have holes located at the proximal and distal ends for passing of neck screw and for fixation to bone by means of locking screws, respectively. The neck screws are inserted into the proximal hole of rod angle with 120, 125, 130, 135 degrees, selectively. The wedge wing in the neck screw prevents the twisting of the neck screw in the femoral head. The fixed & slidable nail cap are fixed in the rod to prevent operation failure due to the excessive motion of neck screw. The fixed nail cap prevents the rotation and movement of neck screw, but slidable nail cap is applicable only for rotation. Meanwhile, the end cap (or short end cap) screws into the threaded end of the nails to prevent bone ingrowth, otherwise newbone in the nail hamper to remove the nail. The end cap is used

*Dyna Locking Trochanteric Nail™***U&I CORPORATION**

primarily, however short end cap which do not protruding out of end of nail also may be used according to patients' conditions.

All implants of *Dyna Locking Trochanteric Nail™* are single use device, supplied non-sterile and manufactured from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136. Specialized instruments made from surgical grade stainless steel are available for the instrumentation and removal of the *Dyna Locking Trochanteric Nail™*.

Intended Use:

The *Dyna Locking Trochanteric Nail™* is intended to be implanted into the intramedullary canal and head of femur for alignment, stabilization, fixation of fractures caused by trauma or disease including followings:

- Pertrochanteric fractures
- Subtrochanteric fractures
- Intertrochanteric fractures
- Comminuted fractures
- Segmental fractures
- Fracture with bone loss
- Proximal and distal fractures
- Non-unions and malunions

Substantial Equivalence:

The *Dyna Locking Trochanteric Nail™* is substantially equivalent to Grosse and Kempf Locking Nail System (K860756), Delta II Femoral Nail (K981529), T2 Femoral Nail (K081152), Proximal Femoral Nail System (K973240), Dynamic Hip Screw (K953607) in design, performance, function and intended use.

1. Comparison technological characteristics

The predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similarities:

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials (Ti-alloy based biocompatible materials)
- The equivalent mechanical performance

2. Performance Testing

The *Dyna Locking Trochanteric Nail™* was tested in a non clinical setting (bench testing) to assess that no new safety and efficiency issues were raised with this device. The testing met all

acceptance criteria and verifies that performance of the *Dyna Locking Trochanteric Nail™* is substantially equivalent to the predicate devices.

The following tests were performed:

- 4-point bend test of rods
- Torsional test of rods
- 3-point bend test of locking screws
- Cutout test of neck screws
- Dynamic compression test of full constructs

3. Conclusion

The data and information provided in this submission support the conclusion that the *Dyna Locking Trochanteric Nail™* is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.



Food and Drug Administration
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Document Control Room --WO66-G609
Silver Spring, MD 20993-0002

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JUN 23 2010

Re: K093707

Trade/Device Name: Dyna Locking Trochanteric Nail™
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB, HTY
Dated: May 24, 2009
Received: May 26, 2009

Dear Gyeong-Je Kwon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K093707

Device Name: *Dyna Locking Trochanteric Nail™*

Indications for Use:

The *Dyna Locking Trochanteric Nail™* is intended to be implanted into the intramedullary canal and head of femur for alignment, stabilization, fixation of fractures caused by trauma or disease including followings:

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Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[Signature] for *mxm*
(Division Sign Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Dyna Locking Trochanteric Nail™ 510(k) Number K093707

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